DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

BKS 01/14/98

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JAN 27 1998

WARNING LETTER

Certified Mail
Return Receipt Requested

Richard Chapman
President and CEO
Finnigan Corporation
2215 Grand Avenue Parkway
Austin, Texas 78728

Dear Mr. Chapman:

We are writing to you because a review of your labeling and promotional material by the Food and Drug Administration (FDA) revealed a serious regulatory problem involving your mass spectrometer system, BreathMat plus. Our review of your labeling and promotional material indicates you are currently marketing this device for the detection of Helicobacter pylori infection in the gastrointestinal tract.

Under a United States law, the Federal Food, Drug, and Cosmetic Act (Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they can offer them for sale. This helps protect the public health by ensuring that newly introduced medical devices are safe and effective or substantially equivalent to other devices already legally marketed in this country.

Although our records indicate you have a cleared premarket notification, K880418, which was found to be substantially equivalent to a general purpose mass spectrometer, we have searched our records and cannot find information that shows you obtained marketing clearance before you began offering the product for the detection of H. pylori. We believe your device when used for the detection of H. pylori is a new intended use and falls under Title 21, Code of Federal Regulations (21 CFR), section 862.2860, mass spectrometer for clinical use. A new premarket notification is required for this intended use in accordance with section 510(k) of the Act and 21 CFR 807.81(a)(3)(ii). This is explained in the ODE guidance document entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device," dated January 10, 1997. The kind of information you need to submit in order to obtain this clearance is described in the enclosed

materials. Depending on our evaluation of this information, we may be able to allow you to legally market the product.

Because you do not have marketing clearance from FDA, your product is presently in violation of the law. In legal terms, the product is considered by the Act to be adulterated under section 501(f)(1)(B) and misbranded under section 502(o). The term "adulterated" means that some aspect of the product does not meet FDA requirements, such as a product not cleared for marketing by the FDA or products not made according to the Quality System Regulation. The term "misbranded" means that records, reports or information about the product do not meet FDA requirements, such as with labeling that makes false or misleading claims or when certain records needed for marketing clearance have not been submitted to the agency.

You should know that this violation of the law may result in FDA taking serious regulatory action without further notice to you. The actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties.

It is necessary for you to take action on this matter now. Please let this office know what steps you have taken to correct the problem within fifteen (15) working days from the date you received this letter. We also ask that you explain how you plan to prevent this from happening again. If you need more time, please let us know why and when you expect to complete your corrections. Please direct your response to Betty Collins, Chief, In Vitro Diagnostic Devices Branch, Center for Devices and Radiological Health, 2098 Gaither Road, HFZ-321, Rockville, MD 20850.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of premarket clearance for your device and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-(800) 638-2041 or through the Internet at http://www.fda.gov

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Broden Staples at (301) 594-4588.

Sincerely yours,

Reva J. Melton

for/ Lillian J. Gill
Director
Office of Compliance
Center for Devices and
Radiological Health

Enclosure